

REMARKS

Rejection under 35 USC § 112, second paragraph

At page 2 of the January 26, 2004 Office Action, it is stated that the "35 U.S.C. 112 rejection is withdrawn." Applicants assume that the Examiner is referring here to the prior rejection under 35 USC § 112, second paragraph.

Withdrawn Claims 36-56 and Claims 57-77

Claims 36-56 are once again said to be withdrawn from consideration. In the Office Action of January 26, 2004 is argued that the prior request for reconsideration of the withdrawn status of these claims is denied because the claims are not dependent on claim 14. This is the same argument that was made in the Office Action of June 19, 2003. Applicants clearly refuted this argument in the Reply filed September 22, 2003. **The Examiner has not responded to these arguments.** Merely restating an assertion, that provides no justification for withdrawing claims from consideration, and failing to respond to Applicants' rebuttal arguments does not in further prosecution.

Applicants agree that claims 36-56 do not depend from claim 14. However, there is no basis set forth in the statutes, rules or even the MPEP that justifies withdrawing claims from consideration simply because they do not depend from an independent claim under examination. If the Examiner persists in denying consideration of these claims, Applicants respectfully request that the Examiner cite some authority that supports the withdrawal of these claims from examination.

Dependency does not determine whether claims are drawn to the same invention. This rationale is akin to arguing that one can only have one independent claim in an application. If there are two independent claims then there is at least one claim which has a different dependency lineage.

The facts show clearly that the subject matter of claims 36-56 are drawn to the same general subject matter as the examined claims. Independent claims 36, 37, 38, and 56 are all directed to methods of contraception in a female mammal. The same is true for examined independent claim 14. Claims 36, 37, 38, and 56 all recite, during a period of at least 28 days

(e.g., 28-84 days), administering a gestagen and during the last 5-10 days of that period administering a gestagen and a natural estrogen. The same is true for examined independent claim 14. The Examiner has presented no rationale as to why these claims reciting these similar features are directed to different inventions.

The subject matter of claims 36, 37, 38, 56, and the claims dependent thereon is undeniably related to the subject matter being examined. There is nothing of record to support the allegation that a separate search is required. There is nothing of record to support that there is any serious burden imposed on the Examiner in examining these claims with the elected subject matter.

As for claims 56-69, it is noted that several of these claims, namely 57, 62, and 67-69, depend directly from claim 14. As for claim 70 - 77, these claims were withdrawn from consideration in the most recent Office Action without any explanation. These claim all depend, directly or indirectly, from claim 14.

Withdrawal of the holding of claims 36-77 as being withdrawn from consideration is respectfully requested. Conversely, if the Examiner maintains this rejection, Applicants request that the Examiner articulate the particular rationale for withdrawing these claims from consideration and to make that determination final so that Applicants can proceed with a petition.

Amendments

Claims 36, 37, 44, and 45 are amended to clarify the language thereof. These amendments are cosmetic in nature and do not narrow the scope of the claims. Claim 48 is amended to depend from claim 46, rather than claim 47. These amendments do not require further search and entry thereof is respectfully requested.

Rejection under 35 USC § 112, first paragraph (Written Description)

In the rejection, it is asserted that claim 14 does not have any specifics. This rejection seems to be directed to the breadth of Applicants' claim 14. But, this assertion presents no rationale as to why the disclosure does not reasonably convey that Applicants had possession of the subject matter claimed at the filing date of the application. Moreover, in fact, claim 14 specifies the host (a female mammal), the components used (a gestagen and a natural estrogen), a time period (at least 28 days), a first phase and a second phase, and which components are

administered during the two phases (a gestagen and a natural estrogen) and the amounts administered (an ovulation-inhibiting amount of a gestagen, and an ovulation-inhibiting amount of a gestagen and a natural estrogen in an amount effective to achieve regular menstrual-like bleeding). This concept is expressly described in the specification. Nothing within the rejection refutes this fact. Thus, the rejection of claim 14 is baseless.

Claim 4 is even more specific. It specifies gestagens for use in the method of claim 14. Once again, this concept is expressly described in the specification. Nothing within the rejection refutes this fact. Thus, the rejection of claim 4 is also baseless.

Thus, the rejection completely fails to present any rationale as to why the concepts expressed in claims 4 and 14 are not reasonably convey by Applicants' disclosure at the filing date of the application. Withdrawal of the rejection is respectfully requested.

Rejection under 35 USC § 112, first paragraph

Claims 3-7 and 14-30 are again rejected under 35 U.S.C. § 112, first paragraph on grounds of alleged lack of enablement. This rejection is once again respectfully traversed.

At page 2 of the Office Action, it is asserted that claims 3-7 and 14-30 are not supported by examples or data. Further, at page 5 of the Office Action, the Examiner asserts that one of ordinary skill in the art "would be at a loss as to where to begin."

Applicants have already refuted this argument, and the Examiner has presented no rebuttal. Contrary to the allegation in the rejection, one of ordinary skill in the art would not "be at a loss as to where to begin." Applicants' specification provides more than adequate information such as examples of specific gestagens, natural estrogens, periods, phases, and amounts, to practice the invention using no more than routine experimentation. Applicants' specification provides examples of gestagens and estrogens for use in the claimed method as well as suitable administration dosages. In addition, in Applicants' examples 1-8 specific method embodiments are described. Thus, the assertion that "no guidance" is provided is clearly wrong. Based on the information in the disclosure and the large amount of information available within this particularly well developed art, one of ordinary skill in the art can practice the claimed invention without undue experimentation.

Various combinations of gestagens and estrogens using different dosage regimes are well known within the art. This is evidence of the well developed nature of the art and the large

amount of past and ongoing research. Such a developed art facilitates routine experimentation.

At page 2 of the Office Action, the Examiner invites the Applicants to "see prior art of record." It is noted that the prior art of record refers to gestagens and estrogens generally. See, for example, the claims of Gast, Konnincx, Hodgen, and Jager. In each of these references, the claims refer both to estrogens and gestagens in general. Thus, using the terms estrogens and gestagens broadly is conventional in this field and demonstrates recognition within the art that the use of such general concepts is sufficient.

At page 2 of the Office Action, it is asserted that "it is impossible to predict contraception" within the scope of Applicants' claims. This is not the test for enablement. Absolute predictability is not required under the statute. Instead, the issue is whether objectively one of ordinary skill in the art can practice the invention using no more than routine experimentation. The rejection presents no rationale to doubt the veracity of statements within Applicants' disclosure and no rationale as to why performing any experimentation to practice the invention would be undue.

Also at page 2 of the Office Action, the Examiner states that the case law cited by Applicants was not persuasive and invites the Applicants "to see the most relevant case laws cited by the Examiner." Applicants respectfully submit that the cited case law can not simply be dismissed because the Examiner wishes to cite other cases. Moreover, Applicants disagree that the cases cited by the Examiner are more relevant.

The allegation that the pharmaceutical art is generally unpredictable does not lead to a conclusion of undue experimentation. Applicants' specification does provide examples of specific gestagens, natural estrogens, periods, phases, and amounts. With such information, one of ordinary skill in this art can readily practice the invention using no more than routine experimentation. In the rejection, *In re Fischer*, 166 USPQ 18 (CCPA 1970), is cited for the proposition that "there is generally a lack of predictability in the pharmaceutical art" and "therefore predicting which compounds within a broad genus would be useful is impossible." However, the relevant language *In re Fischer* is as follows:

In cases involving unpredictable factors, such as most chemical reactions in physiological activities, the scope of enablement obviously varies inversely with the degree of unpredictability of the factors involved.

Fischer does not hold for the implied proposition that, merely because there are

unpredictable factors within an art, the art is necessarily not enabling. Nor does *Fischer* in anyway indicate that within pharmaceutical art, predicting which compounds within a broad genus would be useful is impossible. Furthermore, as mentioned above, absolute predictability is not a requirement for enablement.

The issues in *Fischer* focused on how to make certain compounds. In *Fischer*, the claim invention was an ACTH (adrenocorticotrophic hormone) preparation comprises an active component of any polypeptide that contained at least 24 amino acids of a specified sequence. Also claimed was an ACTH preparation containing at least 1 international unit of ACTH per milligram. The Court held the disclosure to be insufficient to support these claims because the parent application did not inherently or expressly disclose polypeptides that contained more than 39 amino acids, although the claim included all polypeptides having the at least 24 amino acids in the specified sequence. In addition, the specification only disclosed products having potencies of 1.11 to 2.3 international units of ACTH activity per milligram, and the Court held that the record did not support ACTH preparations having potencies much greater than 2.3.

Thus, *Fischer* does not support an assertion of non-enablement with respect to Applicants' claimed invention. One or ordinary skill in the art is clearly objectively enabled as to how to make the compositions used within the claimed method. As noted above, various combinations of gestagens and estrogens for use in different dosage regimes are well known within the art.

In the Office Action, the Examiner quotes from *In re Dreshfield*, 45 USPQ 36 (CCPA 1940) and then asserts that a disclosure should contain representative examples. However, the language quoted by the Examiner refers to the enumeration of a number of members of a chemical group, not specific working examples. Applicants have enumerated members of the classes of gestagens and estrogens in the specification. Moreover, the members of these classes are well known to those of ordinary skill in the art.

The Examiner also cites *In re Riat et al.* 140 USPQ 473 (CCPA 1964). In *Riat*, the invention was concerned an organic water soluble dye stuff. The court held that the claims did comply with 35 USC § 112. There was no reason in the record to suggest that the compounds encompassed by the claims would not be useful as dyestuffs.

We find no suggestion in the record of any compound encompassed by the generic

claims which would not be a dyestuff. The appealed claims are drawn to azo dyes and the Examiner stated that "azo dyes are well known."

The rejection also refers to *In re Barr et al.* 170 USPQ 330 (CCPA 1971). In *Barr*, the Court reversed the rejection asserting that the claims were unsupported by the specification. Specifically, the court stated the following:

Appellants have specifically disclosed how to make and use a large number of compounds and asserted that other compounds similar to the compounds specifically disclosed in certain stated respects may be made and used in the same fashion. We see no reason, on the state of this record, to suspect that their assertion is not accurate or that appellants are not the pioneer inventors that they claim to be.

Thus, *Barr* is consistent with *Marzocchi*, cited by the Applicants (see below), that the burden is on the PTO to initially provide support for its challenge to the veracity of Applicant's statements of enablement within the disclosure.

The remaining two cases cited by the Examiner, *In re Vaeck*, 20 USPQ 2d (Fed. Cir. 1991) and *In re Wright*, 27 USPQ 2d 1510 (Fed. Cir. 1993), both dealt with biotechnology inventions. In both cases, the fields of technology involved, gene expression in cyanobacteria cells and live, non-pathogenic vaccines for pathogenic RNA viruses, were just emerging and thus were not well developed.

Conversely, in the instant case, the field of oral contraception using gestagens and estrogens is a well established field of technology. One of ordinary skill in this relevant art is well aware of procedures used in *in vivo* and *in vitro* testing of oral contraceptive preparations. See, for example, Hodgen (U.S. 5,898,032) regarding *in vivo* studies using monkeys. Moreover, such examples are not needed to objectively enable one of ordinary skill in the art. See, for example, the disclosures of Konnicx, Gast and Jager, all of which disclose oral contraceptives using particular dosage regimens but do not present any *in vivo* or *in vitro* tests. By now it is well settled law that one of ordinary skill in the art need not disclose that which is well known in the art. See, e.g., *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 231 USPQ 81 (Fed. Cir. 1986).

Thus, *in vitro* and *in vivo* test models are well known within this art. Determining the relative efficacy of any particular combination of gestagen and natural estrogen requires no more

than routine experimentation.

All that is required under the statute is objective enablement. It is not required those Applicants' disclosure presents *in vivo* or *in vitro* test results. See, e.g., *In re Marzocchi et al.*, 169 USPQ 367, 369(CCPA 1971):

The first paragraph of §112 requires nothing more than objective enablement. How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is of no importance.

An application disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken in compliance with the enabling requirement of the first paragraph 35 U.S.C. § 112 unless there is reason to doubt the objective truth of statements contained therein relied on for enabling support. *In re Brana*, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995). *Fiers v. Revel*, 984 F.2d 1164, 24 USPQ2d 1601 (Fed. Cir. 1993). Furthermore, as stated in *In re Marzocchi*, 169 U.S.P.Q. 367, 369 (CCPA 1971), the PTO must have adequate support for its challenge to the credibility of Applicant's statements of utility. See also *In re Bundy*, 209 USPQ 48 (CPA 1981).

Also, it is by now well settled law that the test for enablement is not whether any experimentation is needed, but whether or not that experimentation is undue. See, *In re Angstadt*, 190 USPQ 214, 219 (CCPA 1976) in which the art involved (catalysis) was acknowledged to be unpredictable. Even a considerable amount of experimentation, or complex experimentation, is permissible if it is routine. See, e.g., *Ex parte Jackson*, 217 USPQ 804, 807 (POBA 1982) and *In re Wands*, 8 USPQ 2d 1400, 1404 (Fed. Cir. 1988)

In view of the above remarks, it is respectfully submitted that Applicants' disclosure provides more than sufficient guidance to objectively enable one of ordinary skill in the art to make and use the claimed invention with no more than routine experimentation. Withdrawal of the rejection under 35 U.S.C. §112, first paragraph, is respectfully requested.

Rejection(s) Under 35 USC § 103 in view of Weiner et al.

Claims 3-7 and 14-30 are again rejected as being obvious in view Weiner et al. This rejection is once again respectfully traversed.

The following arguments were presented in the Reply file September 22, 2003. The Examiner has not responded to these arguments, but merely restated the rejection.

Weiner et al. disclose a treatment for contraception in which three silastic rods impregnated with 40 mg d-norgestrel are implanted in to the forearms of four patients are left in place for 100-458 days. After about 300 days of treatment, the patients were given a daily oral dose of 50 µg of ethynodiol, a synthetic steroid (see attached excerpt from The Merck Index, 11th Edition (1989)), for 21 days. Weiner et al. disclose that its synthetic estrogen increases the concentration of sex hormone binding globulin in plasma. Weiner et al. does not disclose that the dosage regime provides cycle control and regular menstrual bleeding.

In the Office Action, it is argued that it “does not matter that the prior art uses a synthetic steroid because it teaches the same *method* as the presently claimed invention.” This statement is at best confusing. First, it does matter. The prior art uses a synthetic estrogen and Applicants’ method uses a natural estrogen. The prior art provides no suggestion or motivation to use a natural estrogen in its method. Further, the rejection makes no assertion of any motivation for so modifying the prior art. Motivation is a requisite showing for an obviousness rejection. Merely asserting, without rationale, explanation or support, that motivation is provided by the prior art does not establish that motivation exists. Second, the prior art does not disclose the same method. For example, it uses a synthetic estrogen, not a natural estrogen.

Weiner et al. provide no suggestion of using other combinations of estrogens and gestagens. No other agents other than d-norgestrel and ethynodiol are mentioned. The mere ability to modify a disclosure does not by itself establish obviousness. Instead, there must be some motivation established to modify the prior art. See, e.g., *In re Gordon*, 221 USPQ 1125, 1127 (Fed. Cir. 1984) and *In re Laskowski*, 10 USPQ 2d 1397, 1398 (Fed. Cir 1989). In the instant case, no such motivation is presented.

Weiner et al. fails to provide any motivation that lead one of ordinary skill in the art to modify the disclosed method to achieve a method having a dosage regimen (combination and dosage schedule) in accordance with the claimed invention. An assertion of obviousness is determined from the vantage point of a hypothetical person having ordinary skill in the art to which the patent pertains. To assess this determination, the hypothetical person has the relevant prior art in front of him, but has **no knowledge of Applicants' invention**. Motivation is not established simply by assuming that the prior art can be modified. It is more than this. The

establishment of motivation requires a rationale as to why one would be directed toward making particular modifications.

For the reasons discussed above, withdrawal of the prior art rejection and allowance of the application are respectfully requested.

Respectfully submitted,



Brion P. Heaney (Reg. No. 32,542)
Attorney for Applicant(s)

MILLEN, WHITE, ZELANO & BRANIGAN, P.C.
Arlington Courthouse Plaza I
2200 Clarendon Boulevard, Suite 1400
Arlington, Virginia 22201
(703) 812-5308 [Direct Dial]
E-mail address: heaney@mwzb.com

Filed: May 26, 2004